DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-65

July 2, 2001

Maria M. De Mares, President
Katamaran Corporation
2171 N.W. 24th Court
Miami, Florida 33142

Dear Ms. De Mares:

We completed an inspection of your seafood processing plant, located at the above address, on June 1, 2001 and found that you continue to have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your fresh refrigerated scombrotoxin forming fish products such as mahi-mahi, tuna and escolar to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

You must implement the monitoring procedures listed in your HACCP plan for various scombrotoxin (histamine) forming fish species, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedures listed in your HACCP plan for checking internal temperatures and the adequacy of ice at the receiving critical control point, and for checking temperatures at the storage critical control point to control the food safety hazard of scombrotoxin (histamine) formation.

You must implement the record keeping system listed in your HACCP plan for various scombrotoxin (histamine) forming fish species, to comply with 21 CFR 123.6(c)(7). However, your firm did not record monitoring observations for internal temperatures and the adequacy of ice at the receiving critical control point, and for temperatures at the storage critical control point to control the food safety hazard of scombrotoxin (histamine) formation.

Both of the above deviations were previously brought to your attention at the conclusion of our inspection of your facility on January 22, 1999. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your seafood products and/or enjoin your firm from operating.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice (GMP) regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your HACCP plans, monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,

Emma R. Singleton
Director, Florida District